

Summary 4 - Example Format (Center with Affiliates)											2P30CA654321-50
Clinical Research Protocols											report prepared Friday, July 11, 2003
Outstanding University Cancer Center											
reporting period 1/1/2002 - 12/31/2002											

SECTION 1 (Agent or Device)
NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	ACCRUAL							
											Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
ECOG	Bladder	9638	Saperstein, R.*	2	1/17/99		II	Treat	Study of Paclitaxel plus Carboplatin in Patients with Advanced Carcinoma of the Bladder	4	1	1	0	1	0	0	1	2
POG	Soft	D9902	Schubert, W.	3	1/24/01		N/A	Ancil	Children's group protocol for collecting and banking soft tissue sarcoma specimens	25	5	10	4	4	0	1	9	15
GOG	Cervix	106	Smith, J.	3	1/25/00		II	Treat	Evaluation of Gemcitabine in Persistent or Recurrent Non-Squamous Cell Carcinoma of the Cervix	2	0	1	0	1	0	0	0	2

EXTERNALLY PEER-REVIEWED

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
NCI	Melanoma	9971	Ryabinsky, D.	4	9/24/02		N/A	Corr	Detection of melanoma specific markers in the peripheral blood of pts with stage III or IV melanoma	50	15	15	10	10	0	0	25	25

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
OUCC	Multiple	02-010	Booker, M	3	6/9/01		I	Treat	Ph I trial of subcutaneous and/or oral calcitriol [(1,25-COH)2D3] and Carboplatin in advanced solid tumors	100	12	30	5	22	10	25	27	77
OUCC	Ovary	U12001	Davis, A	5	4/3/00		N/A	Ancil	Vasculogenic Mimicry	50	8	12	0	0	28	34	36	46

		04872							in Ovarian Cancer									
Oucc	Breast	01-11	Raymond, S.	6	6/2/01		Pilot	Treat	Rescue of mucin specific immune memory as an adjunct to autologous stem cell transplantation for breast cancer	5	0	1	1	1	0	0	1	2

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
SuperPharm	Leukemia	SP-990	Gonzalez, R	2	7/3/01		II	Treat	Genasense (Bcl-2 Antisense) Combined with Mylotarg (gemtuzumab ozogamicin) in Elderly Patients with Relapsed Acute Myeloid Leukemia	5	2	2	2	2	2	2	6	6
TechnoCorp	Breast	ID 996	Johnson, H.	2	1/1/01		III	Chemo	TNC400 vs. Placebo for prevention of drug neurotoxicity	15	4	8	2	6	1	3	7	17

SECTION 2 (Non-Agent)

NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	ACCRUAL							
											Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
ECOG	Prostate	CRJ-51	Harshman, A.	2	01/07/95		Pilot	Treat	Randomized pilot study to evaluate whether an outpatient educational and behavioral skills training program will improve pain control in patients who have metastatic or recurrent prostate cancer	225	15	191	19	19	0	0	34	210

EXTERNALLY PEER-REVIEWED

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
NCI	Multi	93-55	Prince, A.	3	3/5/02		N/A	Prev	Teen smoking prevention and cessation via CD ROM program	500	46	210	0	0	95	150	141	360
NCI	Prostate	00-420	Gomez, M.	3	4/20/01		N/A	Treat	Biobehavioral effects of emotional expression in cancer	100	12	53	5	20	2	14	19	87

NIH	Multi	00-037	Blankenship, K.	3	5/8/02		N/A	Treat	An intervention to improve end-of-life pain	90	12	12	6	6	4	4	22	22
NCI	Esophagus	99-315	Shepard, R.	3	3/1/99		N/A	Prev	Smoking cessation intervention for head and neck cancer patients	260	120	221	20	35	18	55	158	311
Susan G. Komen	Breast		Greenberg, S.	3	2/10/99		N/A	Treat	Family Caregiver Interventions	65	0	0	0	0	32	46	32	46
NCI	Breast	95-41	Michaels, L.	3	6/1/95		N/A	Treat	Women's Intervention Nutrition Study (WINS)	N/A	0	90	0	0	10	95	10	185
NCI	Multi	00-4011	Farrell, W.	3	4/25/01		N/A	Prev	Exercise intervention in colorectal polyp patients	300	22	76	65	103	6	30	71	133
Army	Cervix	38552	Garner, F.	3	4/1/99		N/A	Diag	An intervention to improve screening behavior in women at high risk of cervix cancer	140	0	49	0	0	4	31	4	80

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
OUCC	Lip, Oral Cavity	3929	Collyer, E.	3	9/7/00		N/A	Treat	Biobehavioral interventions for oral pain	70	13	13	6	23	0	0	19	36
OUCC	Breast	17-97	*Guralnick, C.	3	10/3/99		N/A	Treat	An exercise intervention program for cancer patients	115	6	74	2	10	4	42	12	126

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
ACS	Multi	7785	Chu, Y.	3	6/7/00		N/A	Treat	Intervention to enhance psychosexual development in adolescents and young adults with cancer	72	10	20	15	30	20	40	45	90

Summary 4 - Example Format (Primary Center)												2P30CA654321-50
Clinical Research Protocols											report prepared	Friday, July 11, 2003
<p style="text-align: center;">Outstanding University Cancer Center</p> <p style="text-align: center;"><i>reporting period 1/1/2002 - 12/31/2002</i></p>												

SECTION 1 (Agent or Device)

NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ECOG	Bladder	9638	*Saperstein, R.	2	1/17/99		II	Treat	Study of Paclitaxel plus Carboplatin in Patients with Advanced Carcinoma of the Bladder	4	0	4
POG	Soft	D9902	Schubert, W.	3	1/24/01		N/A	Ancil	Children's group protocol for collecting and banking soft tissue sarcoma specimens	25	1	1
GOG	Cervix	106	Smith, J.	3	1/25/00		II	Treat	Evaluation of Gemcitabine in Persistent or Recurrent Non-Squamous Cell Carcinoma of the Cervix	2	0	0

EXTERNALLY PEER-REVIEWED

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
NCI	Melanoma	9971	Ryabinsky, D.	4	9/24/02		N/A	Corr	Detection of melanoma specific markers in the peripheral blood of pts with stage III or IV melanoma	50	2	8

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
OUCC	Multiple	02-010	Booker, M	3	6/9/01		I	Treat	Ph I trial of subcutaneous and/or oral calcitriol [(1,25-COH)2D3] and Carboplatin in advanced solid tumors	100	16	51
OUCC	Ovary	U1200104872	Davis, A	5	4/3/00		N/A	Ancil	Vasculogenic Mimicry in	50	0	0

									Ovarian Cancer			
OUCC	Breast	01-11	Raymond, S.	6	6/2/01		Pilot	Treat	Rescue of mucin specific immune memory as an adjunct to autologous stem cell transplantation for breast cancer	5	0	4

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
SuperPharm	Leukemia	SP-990	Gonzalez, R	2	7/3/01		II	Treat	Genasense (Bcl-2 Antisense) Combined with Mylotarg (gemtuzumab ozogamicin) in Elderly Patients with Relapsed Acute Myeloid Leukemia	5	0	1
TechnoCorp	Breast	ID 996	Johnson, H.	2	1/1/01		III	Chemo	TNC400 vs. Placebo for prevention of drug neurotoxicity;double-blind multicenter random trial ph 3 trial in pts w/ metastatic breast ca	15	0	1

SECTION 2 (Non-Agent) NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ECOG	Prostate	CRJ-51	Harshman, A.	2	01/07/95		Pilot	Treat	Randomized pilot study to evaluate whether an outpatient educational and behavioral skills training program will improve pain control in patients who have metastatic or recurrent prostate cancer	225	15	191

EXTERNALLY PEER-REVIEWED

NCI	Multi	93-55	Prince, A.	3	3/5/02		N/A	Prev	Teen smoking prevention and cessation via CD ROM program	500	46	210
NCI	Prostate	00-420	Gomez, M.	3	4/20/01		N/A	Treat	Biobehavioral effects of emotional expression in cancer	100	12	53
NIH	Multi	00-037	Blankenship, K.	3	5/8/02		N/A	Treat	An intervention to improve end-of-life pain	90	2	12
NCI	Esophagus	99-315	Shepard, R.	3	3/1/99		N/A	Prev	Smoking cessation intervention for head and neck cancer patients	260	120	221
Susan G.	Breast		Greenberg, S.	3	2/10/99		N/A	Treat	Family Caregiver	65	0	0

Komen									Interventions			
NCI	Breast	95-41	Michaels, L.	3	6/1/95		N/A	Treat	Women's Intervention Nutrition Study (WINS)	N/A	0	90
NCI	Multi	00-4011	Farrell, W.	3	4/25/01		N/A	Prev	Exercise intervention in colorectal polyp patients	300	22	76
Army	Cervix	38552	Garner, F.	3	4/1/99		N/A	Diag	An intervention to improve screening behavior in women at high risk of cervix cancer	140	0	49

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
OUCC	Lip, Oral Cavity	3929	Collyer, E.	3	9/7/00		N/A	Treat	Biobehavioral interventions for oral pain	70	13	13
OUCC	Breast	17-97	*Guralnick, C.	3	10/3/99		N/A	Treat	An exercise intervention program for cancer patients	115	6	74

INDUSTRY

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ACS	Multi	7785	Chu, Y.	3	6/7/00		N/A	Treat	Intervention to enhance psychosexual development in adolescents and young adults with cancer	72	0	0